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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,088

11/13/2003

Denise L. Doolan

NC 84,381

8196

22245

7590

06/13/2008

NAVAL MEDICAL RESEARCH CENTER

ATTN: (CODE 00L)

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EXAMINER

ZEMAN, ROBERT A

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

06/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/706,088	<b>Applicant(s)</b> DOOLAN ET AL.	
	<b>Examiner</b> ROBERT A. ZEMAN	<b>Art Unit</b> 1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 18-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-11-2008</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's election with traverse of Group I in the reply filed on 1-26-2007 is acknowledged. The traversal is on the ground(s) that both groups relate to a single virus and are classified in the same class and subclass. Additionally, there is no basis to establish that searching both groups would be burdensome. Finally, if the requirement is maintained, Applicant's will be burdened with filing a divisional. This is not found persuasive because Group I is drawn to methods of immunization against malarial diseases whereas Group II is drawn to a two component composition comprising alphavirus replicons. The search of said groups would not be coextensive in scope and hence the searching of both groups would be burdensome. Moreover, different classifications was not the basis of the restriction requirement (see page 3 of the restriction requirement). Finally, whether or not applicant will need to file a divisional application is not a criterion upon which restriction requirements are determined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 are pending. Claims 18-26 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-17 are currently under examination.

### ***Information Disclosure Statement***

The Information Disclosure Statement filed in 4-11-2008 has been considered. An initialed copy is attached hereto.

***Claim Objections***

Claim 3 is objected to because of the following informalities: “Venezuelan” should read “Venezuelan”. Appropriate correction is required.

Claim 7 is objected to because of the following informalities: said claim contains two commas after the term “PfCSP”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rendered vague and indefinite by the use of the terms “PfCSP, PfEXP1, PfSSP2, PfSSP2, PfLSA-3, PfMSP-1, PfAMA-1, PfEBA-175, PfMSP-3, PfMSP-4, PfMSP-5, PfRAP-1, PfRAP-2”. Said terms constitute a laboratory designation engendering no specific sequence. Moreover, said terms are referring to antigens wherein they are purportedly genes. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim 7 recites improper Markush language. The penultimate member of the group needs to be followed by the article "and".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael et al. (WO 98/56919 – IDS filed on 4-11-2008) and Sallberg et al. (U.S. Patent Application Publication US 2002/0165172).

McMichael et al. disclose methods of inducing a CD8 T cell immune response to malarial antigens comprising the administration of a priming composition and a boosting composition wherein said boosting composition comprises a non-replicating or replication impaired pox virus vector (see abstract). Moreover, McMichael et al. further disclose the priming composition can comprise a nucleic acid (either DNA or RNA) that is packaged or in free form (see page 11, lines 4-8), Ty-VLP or a recombinant adenovirus (see page 12, lines 4-5). McMichael et al. further

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disclose that the MVA can be used (see page 12, lines 6-9) in both the priming and boosting compositions (see page 13, line 29-30) and that a variety of viral vectors (including herpes virus) can be used in the priming composition (see page 13, lines 7-16).

McMichael et al. differs from the instant invention in that they do not explicitly disclose the use of priming compositions comprising alphaviruses, generally or Venezuelan Equine Encephalitis Virus specifically. Moreover, McMichael et al. do not explicitly disclose the use of PfCSP, PfEXP1, PfSSP2, PfLSSA-3, PfMSP-1, PfAMA-1, PfEBA-175, PfMSP-3, PfMSP-4, PfMSP-5, PfRAP-1, or PfRAP-2 as the antigens encoded by said Alphaviruses.

Sallberg et al. disclose the use of Alphaviruses in methods for treating or preventing malaria (see paragraph [0050]).

Consequently it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the alphaviruses disclosed by Sallberg et al. in the compositions and methods disclosed by McMichael et al. in order to take advantage of the ability of the Alphaviruses to treat intracellular infections.

One would have had a reasonable expectation of success as alphaviruses have been successfully used in other vaccine compositions and methodologies (see Sallberg et al. al.).

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/  
Primary Examiner, Art Unit 1645  
June 9, 2008